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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,507	02/28/2002	Donald G. Munroe	108074-00023	8368

6449 7590 07/14/2005

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/084,507	Applicant(s) MUNROE ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-51 and 53-64 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 44-51 is/are allowed.
6) ☒ Claim(s) 53-64 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The finality of the rejection of the last Office Action is *withdrawn* in view of the new grounds of rejection set forth below.

Status of Application, Amendments and/or Claims

The amendment filed 17 May 2004 has been entered in full. Claims 44-51, 53-64 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection to claims 44-51 under 35 U.S.C. 112, first paragraph, scope of enablement as set forth at pages 4-5 of the previous Office Action (17 November 2004) is *withdrawn* in view of the amendment (17 May 2004).

The rejection to claims 53-64 under 35 U.S.C. 112, first paragraph, enablement as set forth at pages 6-7 of the previous Office Action (17 November 2004) is *withdrawn*.

The objection to claim 46 as set forth at page 8 of the previous Office Action (17 November 2004) is *withdrawn* in view of the amendment (17 May 2004).

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Specification Objection

The amendment filed 17 December 2003 remains objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. The basis for this rejection is set forth at pages 2-3 of the previous Office Action (17 November 2004).

Claim Rejections - 35 USC § 112, First Paragraph, Written Description, New Matter

Claims 55 and 60 remain rejected under 35 U.S.C. 112, first paragraph, written description new matter. The basis for this rejection is set forth at pages 3-4 of the previous Office Action (17 November 2004).

Applicant maintains the same arguments submitted in the previous amendment (25 August 2004). Applicant argues that it is generally known in the field of signal transduction that activation through the G-protein coupled receptors requires signaling through G-proteins and requires GTP binding. Applicant states that disclosing that EDG is a G-protein coupled receptors provides sufficient support for those skill in the art to understand that measuring GTP γ S binding, indicates whether the tested material is an agonist or antagonists of the receptor. Applicants submit publications.

Applicant's arguments have been fully considered but are not deemed persuasive. The instant claims are drawn to methods for measuring a response indicative of the degree of an agonist activity by specifically measuring GTP γ S binding. The claims encompass assays/experiments to measure GTP binding. These specific utilities were not asserted in the specification as originally filed. The specification, as originally filed, does not provide support for the invention as now claimed. Such limitations recited in

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the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. Submitting references regarding GTP γ S binding is not a substitute for a deficient disclosure.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 53-64 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The basis for this rejection is set forth at pages 7-8 of the previous Office Action (17 November 2004).

Applicant maintains that measuring the compounds listed in the claims, which compounds are downstream from the receptor in a signal transduction pathway, is a well accepted method for determining agonist and/or antagonist activity. Applicant submits that the assays and protocols for each particular compound to be measured are known and accepted by those of skilled in the art.

Applicant's arguments have been fully considered but are not deemed persuasive. "Measuring a response indicative of the degree of an agonist activity" (claim 53) and "measuring a response indicative of the degree of an antagonist activity" (claim 54) is indefinite because it is not clear exactly what response is being measured. The

instant claims fail to recite steps, which differentiate between agonist and antagonist activity.

The dependent claims (claims 55-64) remain indefinite because the steps for identifying an agonist are exactly the same as the steps for identifying an antagonist. Compare claims 55-59 (identifying agonist activity) with claims 60-64 (identifying antagonist activity).

Lastly claims 55 and 60 remain indefinite because of the recitation, "modulation of cellular cyclic AMP levels". It is unclear if "modulation" means increase or decrease. Claims 55 and 60 remain indefinite because the instant claims recite an improper Markush group.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

New Rejections:

Claim Rejections - 35 USC § 112, First Paragraph, Written Description, New Matter

Claims 55 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "wherein the response measure in step (c) is selected from modulation of cellular cyclic AMP".

Applicant's amendment, filed 17 December 2003, asserts that no new matter has been added and directs support to examples 14-19 in the instant specification for the written description for the above-mentioned "limitations". The exact wording or connotation of the instant claims are not readily apparent from said sections. Example 10A teaches the employment of a cAMP inhibition assay to show the presence of functional SIP receptor activity. However, this is not tantamount to a specific utility of a method of identifying a compound as an agonist or antagonist wherein the response is modulation of cellular cyclic AMP levels. This specific utility was not asserted in the specification as originally filed and now changes the scope of the instant disclosure as-filed. The specification, as originally filed, does not provide support for the invention as now claimed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Conclusion


Claims 53-64 are rejected.

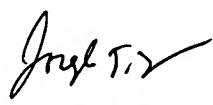
Claims 44-51 would be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RMD
7/11/05


JOSEPH MURPHY
PATENT EXAMINER